**Monoclonal Antibody and Fusion Protein Biosimilars Across Therapeutic Areas: A Systematic Review of Published Evidence**

Ira Jacobs, Danielle Petersel, Lesley G. Shane, Chee-Keng Ng, Carol Kirchhoff, Gregory Finch, Sadiq Lula
*Corresponding author:* Ira Jacobs; Pfizer Essential Health, Pfizer Inc, 235 East 42nd Street, New York, NY, 10017-5755, USA. Email: ira.jacobs@pfizer.com

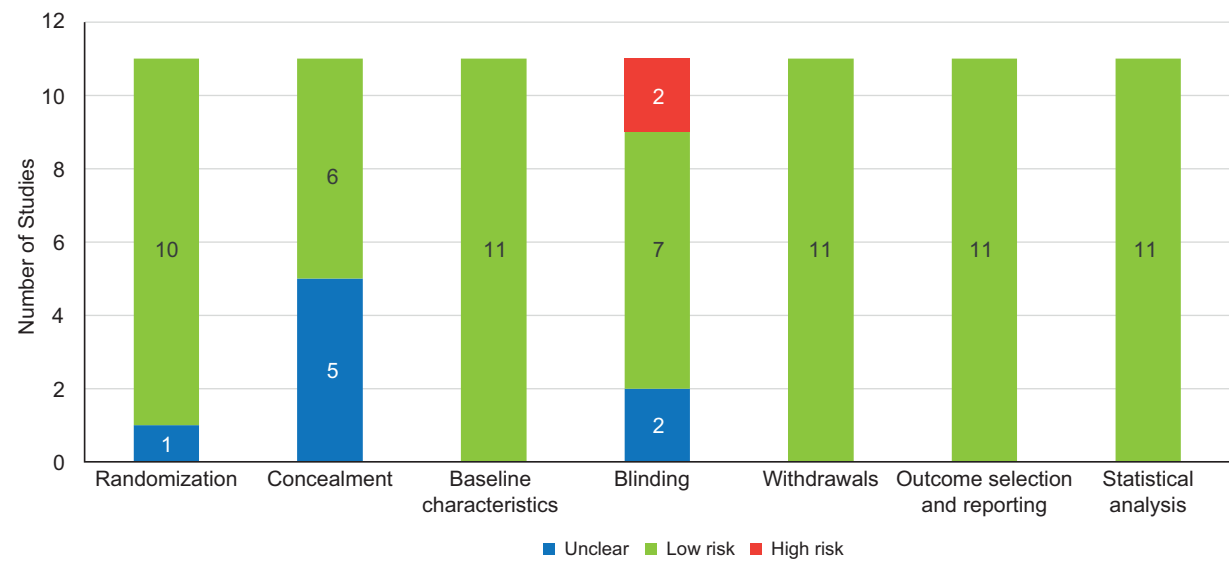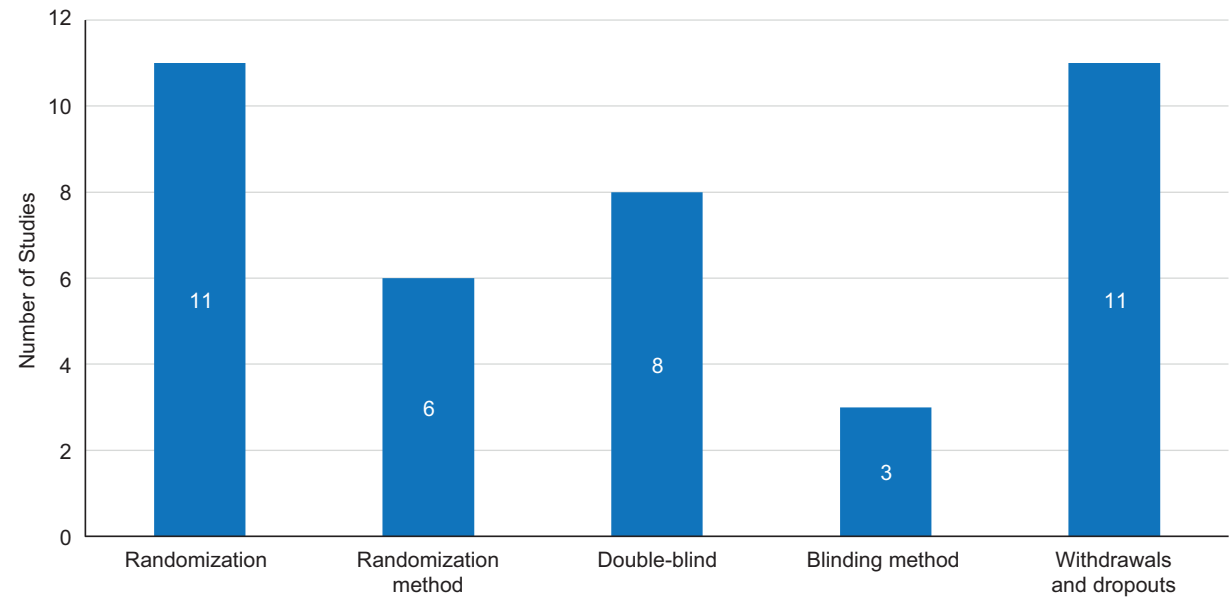## Supplementary Fig. S1 (a) NICE STA assessment of full-text RCTs and (b) Jadad score of full-text RCTs: oncology,[1,2] chronic inflammatory disease,[3-9] and other disease area[10,11] studies.

**a. NICE STA (11 studies)**



**b. Jadad score (11 studies)**



*NICE* National Institute for Health and Care Excellence; *RCT* randomized controlled trial; *STA* single technology appraisal

**References**
1. Wisman LAB, et al. A phase I dose-escalation and bioequivalence study of a trastuzumab biosimilar in healthy male volunteers. Clin Drug Investig. 2014;34(12):887-94.
2. Yin D, et al. A randomized phase 1 pharmacokinetic trial comparing the potential biosimilar PF-05280014 with trastuzumab in healthy volunteers (REFLECTIONS B327-01). Br J Clin Pharmacol. 2014;78(6):1281-90.
3. Jani RH, et al. A prospective, randomized, double-blind, multicentre, parallel-group, active controlled study to compare efficacy and safety of biosimilar adalimumab (Exemptia; ZRC-3197) and adalimumab (Humira) in patients with rheumatoid arthritis. Int J Rheum Dis. 2015; Jul 14 [Epub ahead of print]. doi:10.1111/1756-185X.12711.
4. Park W, et al. A randomised, double-blind, parallel-group, phase 1 study comparing the pharmacokinetics, safety and efficacy of CT-P13 and infliximab in patients with active ankylosing spondylitis: 54 week results from the PLANETAS study. Ann Rheum Dis. 2013;72:A516-7.
5. Yoo DH, et al. A randomised, double-blind, parallel-group study to demonstrate equivalence in efficacy and safety of CT-P13 compared with innovator infliximab when coadministered with methotrexate in patients with active rheumatoid arthritis: the PLANETRA study. Ann Rheum Dis. 2013;72(10):1613-20.
6. Choe J-Y, et al. A randomised, double-blind, phase III study comparing SB2, an infliximab biosimilar, to the infliximab reference product Remicade in patients with moderate to severe rheumatoid arthritis despite methotrexate therapy. Ann Rheum Dis. 2015;74:706-7.
7. Gu NY, et al. Comparative pharmacokinetics and tolerability of branded etanercept (25 mg) and its biosimilar (25 mg): a randomized, open-label, single-dose, two-sequence, crossover study in healthy Korean male volunteers. Clin Ther. 2011;33(12):2029-37.
8. Yi SJ, et al. Comparative pharmacokinetics of HD203, a biosimilar of etanercept, with marketed etanercept (Enbrel®). BioDrugs. 2012;26(3):177-84.
9. Emery P, Vencovský J, Sylwestrzak A, Leszczyński P, Porawska W, Baranauskaite A et al. A phase III randomised, double-blind, parallel-group study comparing SB4 with etanercept reference product in patients with active rheumatoid arthritis despite methotrexate therapy. Ann Rheum Dis. 2015 Jul 6 [Epub ahead of print] doi: annrheumdis-2015-207588.
10. Choi DH, et al. Assessment of the bioequivalence of brand and biogeneric formulations of abciximab for the treatment of acute coronary syndrome: a prospective, open-label, randomized, controlled study in Korean patients. Clin Ther. 2009;31(8):1804-11.
11. Zhou B, et al. Tolerability, pharmacokinetics and pharmacodynamics of CMAB007, a humanized anti-immunoglobulin E monoclonal antibody, in healthy Chinese subjects. MAbs. 2012;4(1):110-9.